

WHAT IS CLAIMED IS

1. A DNA vaccine containing tumor-associated gene and cytokine gene made by incorporating into a vector having a suitable promoter or translation regulatory sequence at least:

a fragment of tumor-associated gene; and

5 a fragment of cytokine gene.

2. The DNA vaccine according to claim 1, wherein said suitable promoter is a mammalian expression promoter.

3. The DNA vaccine according to claim 2, wherein said promoter comprises CMV, PSV or LTR.

10 4. The DNA vaccine according to claim 1, wherein said translation regulatory sequence is an IRES segment.

5. The DNA vaccine according to claim 1, wherein the expression of said tumor-associated gene and cytokine gene are activated by one or more promoters.

15 6. The DNA vaccine according to claim 1, wherein said tumor-associated gene comprises an oncogene.

7. The DNA vaccine according to claim 6, wherein said oncogene comprises neu, met or ras oncogenes.

20 8. The DNA vaccine according to claim 1, wherein said tumor-associated gene comprises a complete or truncated gene segment.

9. The DNA vaccine according to claim 1, wherein said tumor-associated gene comprises a truncated segment of N'-neu gene encoding extracellular domain of neu protein.

25 10. The DNA vaccine according to claim 1, wherein said cytokine gene comprises Interleukin (IL)-2, Interleukin (IL)-4 or GM-CSF gene.

11. The DNA vaccine according to claim 1, wherein said cytokine gene comprises the mature gene segment of Interleukin-2.

12. The DNA vaccine according to claim 1, wherein the genes contained in are arranged in an order that the tumor-associated gene is in front or behind the cytokine gene.

13. The DNA vaccine according to claim 1, wherein said tumor-associated gene and cytokine gene are constructed into a fusion gene controlled by the same promoter.

14. The DNA vaccine according to claim 1, wherein said tumor-associated gene and cytokine gene are constructed in such a way that they are two independent genes controlled respectively by two independent promoters.

15. The DNA vaccine according to claim 1, wherein said tumor-associated gene and cytokine gene are constructed in such a way that they are two independent genes regulated respectively by said promoter and said IRES segment.

16. The DNA vaccine according to claim 1, wherein it is a DNA vaccine containing N'-neu-IL-2 fusion gene controlled by a CMV promoter.

17. The DNA vaccine according to claim 1, wherein said DNA vaccine is carried by retroviral vector, adenoviral vector, adeno-associated viral vector, or liposome, or said DNA vaccine is administered directly in the form of DNA.

18. The DNA vaccine according to claim 1, wherein it is administered by way of subcutaneous injection, intramuscular injection, oral administration, spraying or gene gun injection.

19. A method for preparing DNA vaccine containing tumor-associated gene and cytokine gene, comprising the following steps:

designing a primer sequence containing a proper restriction site;

using polymerase chain reaction (PCR) to amplify and isolate said tumor-associated gene and cytokine gene respectively; and

5 using ligase to co-incorporate respectively the tumor-associated gene and cytokine gene into a vector having a suitable promoter or translation regulatory sequence.

20. The method for DNA vaccine preparation according to claim 19, wherein said promoter is a mammalian expression promoter.

21. The method for DNA vaccine preparation according to claim 19, wherein said promoter comprises CMV, PSV or LTR.

10 22. The method for DNA vaccine preparation according to claim 19, wherein said translation regulatory sequence is an IRES segment.

23. The method for DNA vaccine preparation according to claim 19, wherein the expression of said tumor-associated gene and cytokine gene is activated by one or more promoters.

15 24. The method for DNA vaccine preparation according to claim 19, wherein said tumor-associated gene is an oncogene.

25. The method for DNA vaccine preparation according to claim 24, wherein said oncogene comprises neu, met or ras oncogenes.

20 26. The method for DNA vaccine preparation according to claim 19, wherein said tumor-associated gene comprises a complete or truncated gene segment.

27. The method for DNA vaccine preparation according to claim 19, wherein said tumor-associated gene is a truncated segment of N'-neu gene encoding extracellular domain of neu protein.

25 28. The method for DNA vaccine preparation according to claim 19, wherein said cytokine gene comprises Interleukin (IL)-2, Interleukin (IL)-4 or GM-CSF gene.

29. The method for DNA vaccine preparation according to claim 19, wherein said cytokine gene is the mature gene segment of Interleukin-2.

30. The method for DNA vaccine preparation according to claim 19, wherein the genes contained in it is arranged in an order that the tumor-associated gene is in front or behind the cytokine gene.

31. The method for DNA vaccine preparation according to claim 19, wherein said tumor-associated gene and cytokine gene is constructed into a fusion gene controlled by the same promoter.

32. The method for DNA vaccine preparation according to claim 19, wherein said tumor-associated gene and cytokine gene is constructed in such a way that they are two independent genes controlled respectively by two independent promoters.

33. The method for DNA vaccine preparation according to claim 19, wherein said tumor-associated gene and cytokine gene is constructed in such a way that they are two independent genes controlled respectively by said promoter and said IRES segment.

34. The method for DNA vaccine preparation according to claim 19, wherein said DNA vaccine is a DNA vaccine containing N'-neu-IL-2 fusion gene activated by a CMV promoter.

35. The method for DNA vaccine preparation according to claim 19, wherein said DNA vaccine is carried at least by retroviral vector, adenoviral vector, adeno-associated viral vector, liposome or said DNA vaccine is administered directly in the form of DNA.

36. The method for DNA vaccine preparation according to claim 19, wherein said DNA vaccine may be administered by way of subcutaneous injection, intramuscular injection, oral administration, spraying or gene gun injection.